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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
YANG, NELSON C	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 02/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/970,434	PETERSEN ET AL.	
	Examiner	Art Unit	
	Nelson Yang	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-35,37 and 40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-35,37 and 40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's amendment of claims 21 and 37 is acknowledged and has been entered.

2. Applicant's cancellation of claims 36, 38, 39, 41-75 is acknowledged and has been entered.

3. Claims 21-35, 37, 40 are pending.

Rejections Withdrawn

4. Applicant's arguments, see page 8, filed November 22, 2004, with respect to the rejection of claims 21, 38, 39 are rejected under 35 U.S.C. 112, first paragraph, have been fully considered and are persuasive. The rejection of claims 21, 38, 39 are rejected under 35 U.S.C. 112, first paragraph, has been withdrawn.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 21-26, 31, 32, 35, 37, 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al [US 5,955,029] in view of Murphy et al [US 5,374,522].

With respect to claims 21, 35, 40, Wilding et al teach a cartridge having a sample flow path (claim 1), lysing means (claim 2), filters (column 13, line 41 - column 14, line 13), beads for binding viruses and cell types (column 3, lines 58-62, column 13, lines 1-5), a waste chamber

in fluid communication with the lysing chamber (column 13, lines 13-16), which has an external surface (figures 1, 2), a third chamber (PCR chamber) connected to the lysing means via an analyte flow path for receiving the analyte separated from the sample (claims 1-4), and a flow controller comprising valves that direct fluid flow in the system (claims 2, 3, column 14, lines 14-40). Wilding et al further teach optically detectable labels such as beads may be attached to a binding moiety to enhance detection of the polymerized polynucleotide (column 11, lines 40-49). Wilding et al fail to teach that a transducer coupled to the external surface of the wall.

Murphy et al, however, do teach that ultrasonic energy and lysing beads can be used for lysing cells without destroying the RNA and DNA once released (column 5, lines 5-20, claim 1). Murphy et al further teach that this ultrasonic energy may come from a suitable transducer attached to or in proximity to the well (column 7, lines 25-35). Murphy et al further teach that the low power density of the ultrasound bath of the present invention while sufficient to disrupt cells is not powerful to enough to destroy RNA or DNA once released, and that experiments have shown that the method of the present invention is effective in disrupting cells at room temperature and above, thus allowing cells to be broken open in a rapid, safe, efficient and inexpensive manner (column 8, lines 1-18).

Therefore it would have been obvious in the method of Wilding et al to include beads and a transducer, as suggested by Murphy et al, in the lysing chamber, for lysing cells without destroying the RNA and DNA once released when subjected to ultrasonic energy from a transducer in a rapid, safe, efficient and inexpensive manner.

7. With respect to claims 22-24, Wilding et al further teach mesoscale polynucleotide polymerization reaction chambers which may be used for the rapid amplification of a

polynucleotide, where the presence of amplified polynucleotide product can be detected by means of gel electrophoresis (column 10, lines 55-67). A mesoscale PCR chamber may be microfabricated with multiple sections, connected by flow channel (column 9, lines 50-61). In the first section, a pump delivers the polynucleotide sample and required PCR reagents (column 10, lines 65-67). In the second section, a continual polymerase chain reaction cycle is implemented (column 10, lines 1-5).

8. With respect to claim 25, Wilding et al teach a means for thermally regulating the contents of said chamber whereby the temperature is controlled to amplify said preselected polynucleotide (claim 8) and at least one optical detector for detecting the analyte (column 4, lines 46-62).

9. With respect to claim 26, Wilding et al further teach mesoscale polynucleotide polymerization reaction chambers which may be used for the rapid amplification of a polynucleotide (column 10, lines 55-67).

10. With respect to claim 31, Wilding et al teach sample chambers having a port for introducing a sample into the cartridge, a sample flow path, and a lysing chamber in the sample flow path (columns 15-16, example 2, fig. 12).

11. With respect to claim 32, Wilding et al further teach valves that allow ports connected to flow paths to be opened and closed (column 14, lines 14-25).

12. With respect to claim 37, Murphy et al teach that the walls are deflectable enough that the ultrasound waves are capable of imparting pulsatile motion to the beads, which are located within the chamber (column 7, lines 55-67).

13. Claims 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al [US 5,955,029] in view of Murphy et al [US 5,374,522], as applied to claim 21 above, and further in view of Carlin [*Ultrasonics*, 1960, McGraw-Hill].

With respect to claims 27, 28, Wilding et al and Murphy et al do not specifically teach the use of a wall that is dome-shaped and convex, and sufficiently deflectable to deflect in response to vibratory movements.

However, it would obvious to a person of ordinary skill in the art to use a wall that is dome-shaped and convex, as Carlin teaches the design of plastic lenses from glass, metals, and plastics such as plexiglass or polystyrene, in order to focus beams, which would be very valuable for agitational work, where a great amount of ultrasonic output is necessary (p. 89-90, 61-63).

Therefore it would be obvious to use a wall that is dome-shaped and convex, as taught by Carlin, in the cartridge of Wilding et al, in order to focus beams, where a great amount of ultrasonic output is necessary.

14. With respect to claim 29, the Wilding et al teaches a device where the device ranges from microns to a few millimeters in thickness (column 4, lines 55-60).

15. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al [US 5,955,029] in view of Murphy et al [US 5,374,522], as applied to claim 21 above, and further in view of Bersted et al [US 6,129,879].

Wilding et al and Murphy et al, teach the use of lysing chambers, as discussed above. Wilding et al and Murphy et al do not specify that the lysing chamber comprises a wall comprised of a sheet or film of polymeric material

It is common to find PCR devices comprised of polymeric material such as polypropylene, since the surface of polypropylene is smooth and inert so does not readily bind enzymes and allows for easy recovery of products. Furthermore, Bersted et al teach that other advantages of polypropylene include low cost, ease of processing, strength, chemical inertness and hydrophobicity (column 1, lines 35-44).

Therefore, it would be obvious to use a wall comprised by a sheet or film of polymeric material, as taught by Bersted et al, in the device of Wilding et al, since the surface of polymeric material does not readily bind to enzymes and allows for easy recovery of products.

16. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al [US 5,955,029] in view of Murphy et al [US 5,374,522], as applied to claim 21 above, and further in view of Lynnworth [US 4,335,719].

Wilding et al, Buechler et al, and Murphy et al teach the use of lysing chambers, but fail to teach the use of stiffening ribs.

Lynnworth, however, teaches that in order to increase the transmission through the shield at higher frequencies, or to reduce the mass of the shield, the shield thickness may be reduced considerably. Tube wall thickness as small as 0.1 mm are commonly available for many engineering materials. However, such thin walled tubes are not always adequate structurally, as their reduced stiffness is subject to vibratory motion.

Therefore the thin shield is reinforced or stiffened in one direction by ribs (column 12, lines 20-30). Therefore, it would be obvious to use stiffening ribs in the invention of Wilding et al, as taught by Lynnworth, in order to increase the transmission through the wall at higher frequencies.

17. Claims 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al [US 5,955,029] in view of Murphy et al [US 5,374,522], as applied to claim 21 above, and further in view of Buechler et al [US 6,106,779].

With respect to claims 33-34, Wilding et al teach a cartridge having a sample flow path (claim 1), lysing means (claim 2), filters (column 13, line 41 - column 14, line 13), beads for binding viruses and cell types (column 3, lines 58-62, column 13, lines 1-5), a waste chamber in fluid communication with the lysing chamber (column 13, lines 13-16), which has an external surface (figures 1, 2), a third chamber (PCR chamber) connected to the lysing means via an analyte flow path for receiving the analyte separated from the sample (claims 1-4), and a flow controller comprising valves that direct fluid flow in the system (claims 2, 3, column 14, lines 14-40). Wilding et al fail to teach that the filter and beads are contained in the lysing chamber, nor does Wilding et al teach a transducer coupled to the external surface of the wall.

Buechler et al, however, teach that the use of filters and meshes for the lysing of cells and for removing component material (column 23, lines 10-35).

Therefore it would have been obvious in the method of Wilding et al to include filters, as suggested by Buechler et al in the lysing chamber, for lysing cells while also removing component material.

Double Patenting

18. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible

harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

19. Claims 21-30, 33-35 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,664,104. For example, U.S. Patent No. 6,664,104 teach a device for extracting an analyte from a sample, the device comprising a cartridge having: a first flow path that includes a flow-through chip for extracting the analyte from the sample, the chip comprising a body having formed therein: an extraction chamber; at least one inlet port in fluid communication with the extraction chamber; at least one outlet port in fluid communication with the extraction chamber, wherein the inlet and outlet ports permit liquid flow through the extraction chamber and out of the chip; and an array of microstructures extending into the extraction chamber for capturing the analyte from the sample as the sample flows through the chip and for subsequently releasing the captured analyte into an elution fluid as the elution fluid flows through the chip, wherein each of the microstructures has an aspect ratio (ratio of height to width or diameter) of at least 2:1; an elution flow path for eluting the captured analyte from the chip, wherein the elution flow path passes through the chip and diverges from the first flow path after passing through the chip; and at least

one flow controller positioned downstream of the at least one outlet port to direct the remaining sample fluid, from which the analyte has been separated, to flow in the first flow path after the sample flows through the chip and to direct the eluted analyte to flow in the diverging elution flow path (claim 1). The device further comprises beads in the lysing chamber for rupturing the sample components (claim 34).

20. Claims 21, 26-30 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application No. 10/006,904, claims 1-25 of copending Application No. 10/006,848 in view of Wilding et al [US 5,955,029].

Although the conflicting claims are not identical, they are not patentably distinct from each other because the applications discuss a device for lysing components of a fluid sample, the device comprising: a) a cartridge having: i) an inlet port for introducing the sample into the cartridge; ii) a lysing chamber containing a membrane or filter for capturing the sample components as the sample flows through the lysing chamber; iii) an outlet port for exit of the sample from the lysing chamber; and iv) beads in the lysing chamber for rupturing the sample components; and b) an ultrasonic transducer for transferring ultrasonic energy to the lysing chamber to agitate the beads and thereby rupture the components, wherein the transducer is coupled to a wall of the lysing chamber. Furthermore it would be obvious for the outlet port to connect to waste and reaction chambers for detection and amplification of polynucleotides in the sample (column 10, lines 54-65), thus providing a small, mass produced device for performing polynucleotide polymerization reaction to enable the rapid amplification of a polynucleotide in a sample (column 3, lines 10-15).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

21. Applicant's arguments filed November 22, 2004 have been fully considered but they are not persuasive. Specifically, Murphy et al do also teach that ultrasonic energy may come from a suitable transducer attached to or in proximity to the well (column 7, lines 25-35), which would be the lysing chamber in the device of Wilding et al. Therefore, applicant's argument that Murphy et al do not teach a transducer attached to the external surface of the wall is not found persuasive.

Conclusion

22. No claims are allowed.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

24. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nelson Yang
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Art Unit 1641

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02/04/05